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CONFIDENTIAL

K002392

# Ventrix® True Tech
# Ventricular Tunneling Pressure Monitoring Kit

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Submitter's name and address:**

Integra NeuroSciences
5955 Pacific Center Blvd.
San Diego, CA 92121

**Contact person and telephone number:**

Nancy A. Mathewson, Esq.
Manager, Regulatory Affairs
(858) 455-1115

**Date summary was prepared:**

August 4, 2000

**Name of the device:**

| | |
|---|---|
| **Proprietary name:** | Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit |
| **Common name:** | Intracranial Pressure Monitoring Kit |
| **Classification name:** | Intracranial Pressure Monitoring Device Product Code GWM |

**Substantial Equivalence:**

The Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit, Model NL960-V, is substantially equivalent in function and intended use to the Ventrix® Ventricular Tunneling Pressure Monitoring Kit, Model NL950-V.

**Device Description:**

The Integra NeuroSciences Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit (NL960-V) contains one (1) transducer tipped catheter with stylet inserted, attached to an intermediate cable. The catheter/cable assembly is used to continuously monitor intracranial pressure and drain cerebrospinal fluid.

In addition to the catheter and cable, the following accessories are included in the kit:

- Stainless steel trocar with scalp tunneling sheath
- Two (2) suture loops
- 7mm drill bit with drill stop
- Allen wrench
- Drainage assembly with double suture loop
- Protective cap for tunneled connector
- Directions for use (DFU)

The catheter/cable assembly interfaces with most bedside patient monitoring instruments using the Ventrix® ICP Monitor (NL950-100) and Monitor Interface Cable (NL950-MC). The catheter is radiopaque except for the last 5mm of the catheter's distal tip.

**Statement of Intended Use:**

Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kits are intracranial pressure monitoring catheters and accessories intended to be used on patients that require continuous invasive intracranial pressure monitoring and/or cerebrospinal drainage.

## Comparison of technological characteristics to the predicate device:

### Table I – NL950-V and NL960-V Comparison Chart

| Technological Characteristic | Ventrix® NL950-V | Ventrix® NL960-V |
|---|---|---|
| Indications for Use | Indicated for use on patients that require continuous invasive intracranial pressure monitoring and/or cerebrospinal drainage. | Identical to the Ventrix® NL950-V |
| System Specifications | Accuracy: ±2 mmHg from 0 to 20 mmHg<br>±10% from 20 to 100 mmHg<br><br>Zero Point : 2 mmHg over first 24 hrs<br>Drift 1mmHg/24 hrs over next 48 hrs<br><br>Temp Stability: 5 mmHg maximum change over operating range of Ventrix ICP monitor | Identical to the Ventrix® NL950-V |
| Sensor Design | Fabry-Perot Optical Sensor | Identical to the Ventrix® NL950-V |
| Connector Design | Standard Radiall EC Fiberoptic Connector | Identical to the Ventrix® NL950-V |
| Method of Catheter Tunneling | Catheter tunneled through trocar/sheath assembly* | Identical to the Ventrix® NL950-V |
| System Monitor | Ventrix® ICP Monitor, Model Number NL950-100 and associated cables | Identical to the Ventrix® NL950-V |
| Packaging Method and Materials | Tyvek lid heat sealed to a thermoform tray inserted into a header bag. Boxed individually. | Identical to the Ventrix® NL950-V |
| Sterilization Process | 100% Ethylene Oxide to a sterility assurance level of $10^{-6}$. | Identical to the Ventrix® NL950-V |

*The original Ventrix Catheter was tunneled towards the insertion site, while the Ventrix True Tech Catheter is tunneled away from the site.

## 1. Safety:

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the Ventrix® True Tech catheter are safe for its intended use.

In addition, the Ventrix® True Tech catheter was subjected to extensive mechanical testing, which included pressure, pull and bend tests. Results of the testing showed that the catheter design was mechanically sound and safe for its intended use.

The Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

## 2. Conclusion:

The Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit is substantially equivalent to the unmodified Ventrix® Ventricular Tunneling Pressure Monitoring Kit. The modifications do not affect the intended use or the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2000

Ms. Nancy Mathewson
Manager, Regulatory Affairs
Integra NeuroSciences
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K002392
Trade Name: Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit, Model NL960-V
Regulatory Class: II
Product Code: GWM
Dated: August 4, 2000
Received: August 7, 2000

Dear Ms. Mathewson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# APPENDIX B

## Indications for Use Statement

**510(k) Number** K002392

**Device Name** Ventrix® True Tech Ventricular Tunneling Pressure Monitoring Kit, Model NL960-V

**Indications for Use**

Ventrix True Tech Ventricular Tunneling Pressure Monitoring Kits, Model NL960-V are intracranial pressure monitoring catheters and accessories intended to be used on patients that require continuous invasive intracranial pressure monitoring and/or cerebrospinal drainage.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801. 109) OR Over-The-Counter Use _____

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002392